

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
THIS DOCUMENT RELATES TO ALL CASES	HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)

CERTIFICATION OF ADAM M. SLATER IN SUPPORT OF  
PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE  
THE LIABILITY OPINION OF DR. SUSAN BAIN

ADAM M. SLATER, hereby certify as follows:

1. I am an attorney at law within the State of New Jersey and a partner with the law firm of Mazie Slater Katz & Freeman, LLC, and serve as Plaintiffs' Co-Lead Counsel. I am fully familiar with the facts and circumstances of these actions. I make this Certification in support of Plaintiffs' opposition to Defendants' motion to exclude the liability opinion of Dr. Susan Bain.
2. Attached hereto as **Exhibit 1** is a true and accurate copy of Kulka Vera, *First Regulatory Science Doctorate at USC* (Apr. 21, 2008).
3. Attached hereto as **Exhibit 2** is a true and accurate copy of USC, *Doctorate of Regulatory Science (DRSc)* (Feb. 26, 2010, via <https://archive.org/web/>).
4. Attached hereto as **Exhibit 3** is a true and accurate copy of Keck, *Clinical and Regulatory Affairs* (Mar. 22, 2015, via <https://archive.org/web/>).
5. Attached hereto as **Exhibit 4** is a true and accurate copy of Keck, *Susan Bain, DRSc* (Mar. 16, 2015, via <https://archive.org/web/>).

6. Attached hereto as **Exhibit 5** is a true and accurate copy of Keck, *Introduction to US Food and Drug Law* (Mar. 22, 2015, via <https://archive.org/web/>).

7. Attached hereto as **Exhibit 6** is a true and accurate copy of Keck, *Drug and Biologic Regulations* (Mar. 22, 2015, via <https://archive.org/web/>).

8. Attached hereto as **Exhibit 7** is a true and accurate copy of USC, *Frequently Asked Questions*.

9. Attached hereto as **Exhibit 8** is a true and accurate copy of USC, *MS in Medical Product Quality*.

10. Attached hereto as **Exhibit 9** is a true and accurate copy of USC, *Course Descriptions: Auditing Principles: Auditing Principles*.

11. Attached hereto as **Exhibit 10** is a true and accurate copy of USC, *Course Descriptions: Quality Assurance for Drugs and Biologics*.

12. Attached hereto as **Exhibit 11** is a true and accurate copy of USC, *Course Descriptions: Quality Systems and Standards*.

13. Attached hereto as **Exhibit 12** is a true and accurate copy of USC, *Course Descriptions: Validations Requirements for Medical Products*.

14. Attached hereto as **Exhibit 13** is a true and accurate copy of *Geiss v. Target Corp.*, No. 09–2208 (RBK/KMW), 2013 WL 4675377 (D.N.J. 2013).

15. Attached hereto as **Exhibit 14** is a true and accurate copy of Springer, *Therapeutic Innovation & Regulatory Science*.

16. Attached hereto as **Exhibit 15** is a true and accurate copy of Keck, *Current Issues for FDA Regulated Products* (Sept. 5, 2015, via <https://archive.org/web/>).

17. Attached hereto as **Exhibit 16** is a true and accurate copy of ScienceDirect, *An Overview of FDA Regulated Products, From Drugs and Cosmetics to Food and Tobacco*.

18. Attached hereto as **Exhibit 17** is a true and accurate copy of Elsevier, *An Overview of FDA Regulated Products, From Drugs and Cosmetics to Food and Tobacco*.

19. Attached hereto as **Exhibit 18** is a true and accurate copy of ZHP01862672 (ZHP232).

20. Attached hereto as **Exhibit 19** is a true and accurate copy of FDA, *Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches* (Dec. 2008).

21. Attached hereto as **Exhibit 20** is a true and accurate copy of the relevant portion of HUAHAI-US00007752.

22. Attached hereto as **Exhibit 21** is a true and accurate copy of the relevant portion of PRINSTON0008001.

23. Attached hereto as **Exhibit 22** is a true and accurate copy of FDA, *Compliance Program Guidance Manual: Chapter 56 – Drug Quality Assurance* (Sept. 11, 2015).

24. Attached hereto as **Exhibit 23** is a true and accurate copy of PRINSTON00000001.

25. Attached hereto as **Exhibit 24** is a true and accurate copy of FDA, *FDA Statement on FDA's ongoing investigation into valsartan impurities and recalls and an update on FDA's current findings*, p. 4 (Aug. 30, 2018).

26. Attached hereto as **Exhibit 25** is a true and accurate copy of the FDA's November 29, 2018 Warning Letter, PRINSTON00077339.

27. Attached hereto as **Exhibit 26** is a true and accurate copy of Jinsheng Lin's July 27, 2017 email, ZHP0019057 (ZHP 296).

28. Attached hereto as **Exhibit 27** is a true and accurate copy of *Glynn v. Merck Sharp & Dohme Corp.*, Nos. 11–5304, 08–08, 2013 WL 1558690 (D.N.J. April 10, 2013).

29. Attached hereto as **Exhibit 28** is a true and accurate copy of the relevant portion of IARC, *Some Nitroso Compounds* (Lyons, Fr. 1978).

30. Attached hereto as **Exhibit 29** is a true and accurate copy of Long & Meek, *Concise International Chemical Assessment Document 31: N,N-Dimethylformamide* (WHO 2001).

31. Attached hereto as **Exhibit 30** is a true and accurate copy of Juillard, *Dimethylformamide: Purification, Tests For Purity And Physical Properties*, Int'l Union of Pure and Applied Chem (Pergamon Press 1977).

32. Attached hereto as **Exhibit 31** is a true and accurate copy of FDA, *FDA presents interim limits of nitrosamines in currently marketed ARBs* (Dec. 19, 2018).

33. Attached hereto as **Exhibit 32** is a true and accurate copy of EPA, *N-Nitrosodimethylamine*.

34. Attached hereto as **Exhibit 33** is a true and accurate copy of EPA, *N-Nitrosodiethylamine*.

35. Attached hereto as **Exhibit 34** is a true and accurate copy of USP, Summary, Highlights and Timeline of General Chapter <1469> Nitrosamine Impurities (July 20, 2018).

36. Attached hereto as **Exhibit 35** is a true and accurate copy of Min Li's April 20, 2021 deposition transcript in this case.

37. Attached hereto as **Exhibit 36** is a true and accurate copy of PRINSTON00075797 (ZHP 210).

38. Attached hereto as **Exhibit 37** is a true and accurate copy of ZHP00662283 (ZHP 212).

39. Attached hereto as **Exhibit 38** is a true and accurate copy of ZHP's May 13, 2022 Stipulation in this case.

40. Attached hereto as **Exhibit 39** is a true and accurate copy of Fengtian Xue's deposition transcript in this case.

41. Attached hereto as **Exhibit 40** is a true and accurate copy of Lee, Shen, & Grinberg, *Identification and Control of Impurities for Drug Substance Development using LC/MS and GC/MS*, J. of Liquid Chromatography & Related Tech. (Aug. 7, 2008).

42. Attached hereto as **Exhibit 41** is a true and accurate copy of ZHP01746278.

43. Attached hereto as **Exhibit 42** is a true and accurate copy of SYNCORES00001458.

44. Attached hereto as **Exhibit 43** is a true and accurate copy of SOLCO00027588.

45. Attached hereto as **Exhibit 44** is a true and accurate copy of Dr. Hecht's July 6, 2021 Expert Report.

46. Attached hereto as **Exhibit 45** is a true and accurate copy of Dr. Hecht's October 31, 2022 Expert Report.

47. Attached hereto as **Exhibit 46** is a true and accurate copy of ZHP00359798.

48. Attached hereto as **Exhibit 47** is a true and accurate copy of ZHP01390018.

49. Attached hereto as **Exhibit 48** is a true and accurate copy of Peng Dong's March 29, 2021 deposition transcript in this case.

50. Attached hereto as **Exhibit 49** is a true and accurate copy of ICH Q8, *Pharmaceutical Development*.

51. Attached hereto as **Exhibit 50** is a true and accurate copy of ICH Q9, *Quality Risk Management*.

52. Attached hereto as **Exhibit 51** is a true and accurate copy of ICH Q3A, *Impurities in New Drug Substances*.

53. Attached hereto as **Exhibit 52** is a true and accurate copy of Peng Dong's March 31, 2021 deposition transcript in this case.

54. Attached hereto as **Exhibit 53** is a true and accurate copy of David Chesney's January 12, 2022 report in this case.

55. Attached hereto as **Exhibit 54** is a true and accurate copy of David Chesney's March 21, 2022 deposition transcript in this case.

56. Attached hereto as **Exhibit 55** is a true and accurate copy of USP, *General Notices and Requirements*.

57. Attached hereto as **Exhibit 56** is a true and accurate copy of *Player v. Motiva Enterprises LLC*, No. Civ. 02-3216(RBK), 2006 WL 166452 (D.N.J. Jan. 20, 2006).

**MAZIE SLATER KATZ & FREEMAN, LLC**  
Attorneys for Plaintiffs

By: /s/ Adam M. Slater

Dated: April 11, 2023